

Patent Application

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. of: Jonathan S. Stinson

Art Group: 3738

Serial No.: 08/904,467

Examiner: Suzette Jackson  
(Prior Appl.)

Serial No.: (New Application)

Filed:

Atty. Docket: 23,369-129

For: Process For Making Bioabsorbable Self-Expanding Stent

PRELIMINARY AMENDMENT

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Before considering this application on the merits, please amend this application as follows:

In the Specification:

To confirm an instruction in the accompanying Request for Divisional Application:  
At the first page, immediately after the title, add the following paragraph:

-- This is a divisional of copending application Serial No. 08/904,467 entitled  
"Bioabsorbable Self-Expanding Stent," filed August 1, 1997 --.

On page 14 at line 7, after "covering", insert -- 15 --.

On page 31 at line 15, after "vessel.", insert -- An extension to 45 extends from side  
port 41 to an opening 42 --.; at line 23 after "tube 30.", insert -- "A tip 31 is disposed at the  
distal end of tube 30.--; at line 30 after "stent 10.", insert -- Holes 59 are located in the  
double wall section of the holes 55. --

On page 32 beginning after line 7, insert the following paragraph:

-- Figure 11 illustrates a delivery device with an outer tube 61 including member 63 and an inner tube 62 including members 64, 65. Stent 10 maybe disposed in region 66 and one position of member 65 is shown at about region 67. Member 64 may move in the direction of arrow 68 to push the stent out through end 70 into contact with the interior of wall 72. The stent 10 is shown as lines 69, 71. The end 70 maybe moved by moving member 63 in the direction of arrow 73.--

In the Claims:

Cancel claim 1, without prejudice.

To confirm an instruction in the accompanying Request for Divisional Application: cancel claims 2-29, without prejudice.

Add the Following Claims:

30. A process for making a prosthesis, including:

providing a plurality of elongate filaments comprising a bioabsorbable material selected from the group consisting of: polydioxanone, polycaprolactone, polygluconate, polylactic acid-polyethylene oxide copolymers, modified cellulose, collagen, poly(hydroxybutyrate), polyanhydride, polyphosphoester, poly(amino acids), poly-L-lactide, poly-D-lactide, polyglycolide, poly(alpha-hydroxy acid) and combinations thereof;

braiding the filaments on a first mandrel having a first diameter to form a tubular, radially compressible prosthesis structure;

disposing the prosthesis structure on a second mandrel having a second diameter less than the first diameter; and

while the prosthesis structure is so disposed, annealing the prosthesis structure at a temperature between a glass-transition temperature of the bioabsorbable material and a melting temperature of the bioabsorbable material, to form an annealed prosthesis structure having an annealed diameter D when in a free state, less than an initial diameter of the prosthesis structure before said annealing, the annealed prosthesis structure further being

radially compressible to reduced diameters less than the annealed diameter D and radially self-expandable from the reduced diameters.

31. The process of claim 30 wherein:

the bioabsorbable material is selected from the group consisting of poly-L-lactide, poly-D-lactide, polyglycolide, and their combinations.

32. The process of claim 30 wherein:

the first diameter is in the range of 3-30 mm, and the second diameter is in the range of 0.2-10 mm.

33. The process of claim 30 wherein:

said braiding comprises winding the filaments to form a braid angle of from about 120 degrees to about 150 degrees.

34. The process of claim 30 wherein:

said annealing is performed for a time period between about five minutes and about two hours.

35. The process of claim 34 wherein:

said time period is between about 10 minutes and about 20 minutes.

36. The process of claim 30 wherein:

said annealing is performed at an annealing temperature in the range of 60-180 degrees C.

37. The process of claim 36 wherein:

the annealing temperature is in the range of 130-150 degrees C.

38. The process of claim 30 wherein:

said annealing further includes selecting the annealed diameter D based on a predetermined radially outward force to be provided by the annealed prosthesis structure when radially compressed to a predetermined fraction of the annealed diameter D.

39. The process of claim 38 further including:

braiding first and second tubular test structures substantially similar to the unannealed prosthesis structure on the first mandrel;

annealing the first and second tubular test structures on respective first and second test mandrels having different diameters, to form respective first and second annealed test structures having different annealed diameters  $D_1$  and  $D_2$ ;

loading the first annealed test structure, radially compressed, into a delivery system, deploying the first annealed test structure from the delivery system, then measuring a radially outward force exerted by the deployed first test structure when radially constrained to a predetermined fraction of annealed diameter  $D_1$ , thereby to obtain a first radial force value;

loading the second annealed test structure, radially compressed, into the delivery system, deploying the second annealed test structure from the delivery system, then measuring a radially outward force exerted by the deployed second test structure when radially constrained to said predetermined fraction of annealed diameter  $D_2$ , thereby to obtain a second radial force value; and

using the first and second annealed diameters  $D_1$  and  $D_2$  and the first and second radial force values to compute and thereby select an annealed diameter  $D$  corresponding to the predetermined radially outward force.

40. The process of claim 39 wherein:

said using the first and second annealed diameters and radial force values comprises deriving from said annealed diameters and the radial force values a linear equation relating annealed diameters to the radial force values corresponding to the radial force exerted by tubular test structures having the annealed diameters when radially compressed to said predetermined fraction of the annealed diameters.

41. The process of claim 40 wherein:

said predetermined fraction of the annealed diameters is one-half, and the linear equation relating the annealed diameters  $D$  to the corresponding radial force values  $RF$  is:

$$RF = -15D + 491 \pm 20.$$

42. For prosthesis structures of the type having elongated bioabsorbable filaments braided on a first mandrel and then annealed on a second mandrel to form annealed tubular structures having annealed diameters when in a free state, radially compressible to reduced diameters less than their annealed diameters, and radially self-expandable from the reduced diameters; a process for selecting an annealed diameter based on a predetermined radially outward force to be provided by a selected annealed tubular structure when radially compressed to a predetermined fraction of the annealed diameter, said process including:

providing first and second prosthesis structures having a first diameter and being of the type formed by braiding bioabsorbable filaments on a first mandrel;

annealing the first prosthesis structure on a first test mandrel to form a first annealed test structure having an annealed diameter  $D_1$  less than the first diameter;

annealing the second prosthesis structure on a second test mandrel different in diameter from the first test mandrel, to form a second annealed test structure having an annealed diameter  $D_2$  less than the first diameter and different from annealed diameter  $D_1$ ;

radially compressing the first annealed test structure to a reduced diameter  $D_3$  less than diameters  $D_1$  and  $D_2$ , allowing the first test structure to radially self-expand to a predetermined fraction of annealed diameter  $D_1$ , then measuring a radially outward force exerted by the first test structure when at the predetermined fraction of annealed diameter  $D_1$  to obtain a first radial force value;

radially compressing the second annealed test structure to said diameter  $D_3$ , allowing the second test structure to self-expand to said predetermined fraction of annealed diameter  $D_2$ , then measuring a radially outward force exerted by the second test structure when at the predetermined fraction of annealed diameter  $D_2$  to obtain a second radial force value; and

using the first and second annealed diameters  $D_1$  and  $D_2$  and the first and second radial force values to compute and thereby select an annealed diameter  $D$  corresponding to a predetermined radially outward force.

43. The process of claim 42 wherein:

said using the first and second annealed diameters and radial force values comprises deriving from said annealed diameters and the radial force values a linear equation relating annealed diameters to the radial force values corresponding to the radial force exerted by tubular test structures having the annealed diameters when radially compressed to said predetermined fraction of the annealed diameters.

44. The process of claim 43 wherein:

the predetermined fraction of the annealed diameters is one-half, and the linear equation relating and annealed diameters  $D$  to the corresponding radial force values  $RF$  is:

$$RF = -15D + 491 \pm 20.$$

45. A process for making a prosthesis, including:

braiding a plurality of elongate bioabsorbable filaments on a first mandrel having a first diameter to form a tubular, radially compressible prosthesis structure;

disposing the prosthesis structure on a second mandrel having a second diameter less than the first diameter; and

while the prosthesis structure is so disposed, annealing the prosthesis structure at a temperature between a glass transition temperature of the bioabsorbable material and a melting temperature of the bioabsorbable material, to form an annealed prosthesis structure having an annealed diameter  $D$  when in a free state less than an initial diameter of the prosthesis structure before said annealing, the annealed prosthesis structure further being radially compressible to reduced diameters less than the annealed diameter  $D$  and radially self-expandable from the reduced diameters.

46. The process of claim 45 wherein:

The elongate bioabsorbable filaments comprise a material selected from the group consisting of: polydioxanone, polycaprolactone, polygluconate, polylactic acid-polyethylene oxide copolymers, modified cellulose, collagen, poly(hydroxybutyrate), polyanhydride, polyphosphoester, poly(amino acids), poly-L-lactide, poly-D-lactide, polyglycolide, poly(alpha-hydroxy acid) and combinations thereof.

47. The process of claim 45 wherein:

said annealing is performed at annealing temperatures within the range of 60 degrees C. to 180 degrees C.

48. The process of claim 45 wherein:

said annealing is performed for a time period between about five minutes and about two hours.

49. The process of claim 45 wherein:

said annealing further includes selecting the annealed diameter D based on predetermined radially outward force to be exerted by the annealed prosthesis structure when radially compressed to a predetermined fraction of the annealed diameter D.

REMARKS

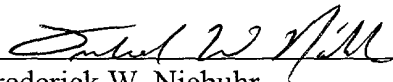
The foregoing amendments to the specification correspond to similar amendments made to the specification in prior application Serial No. 08/904,467.

The applicant respectfully requests entry of the amendments to the specification and claims, and consideration of claims 30-49 on the merits.

Respectfully submitted,

Schneider (USA) Inc

Date: April 25, 2001

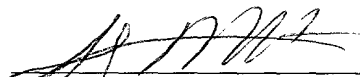
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CERTIFICATE OF MAILING

Pursuant to 37 CFR 1.10, I hereby certify that this Preliminary Amendment is being deposited with the U.S. Postal Service by express mail, post office to addressee service, addressed to: Commissioner for Patents, Washington, D.C. 20231, on the date of deposit and under the mailing label number indicated below.

Date of Deposit: April 25, 2001

Mailing Label No.: EL416124247US

  
GERALYN M. VITA

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FIG. 1

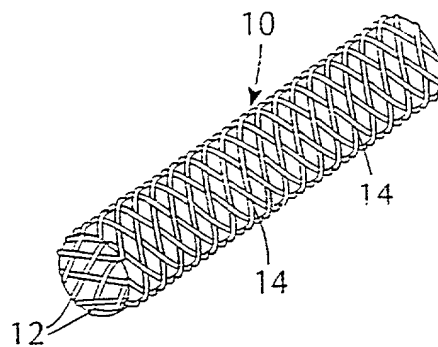


FIG. 2

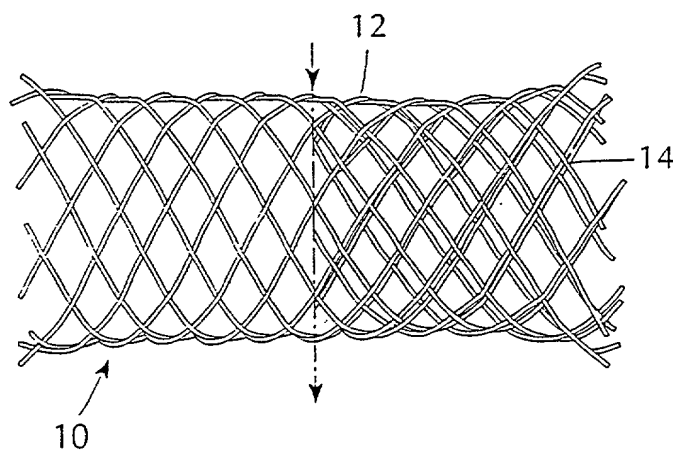


FIG. 3

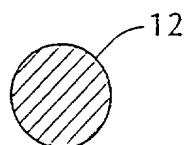




Fig. 11

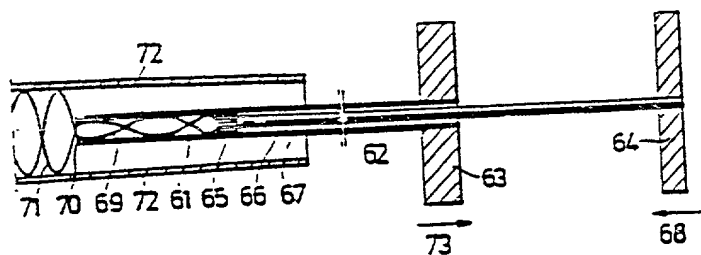


FIG. 12

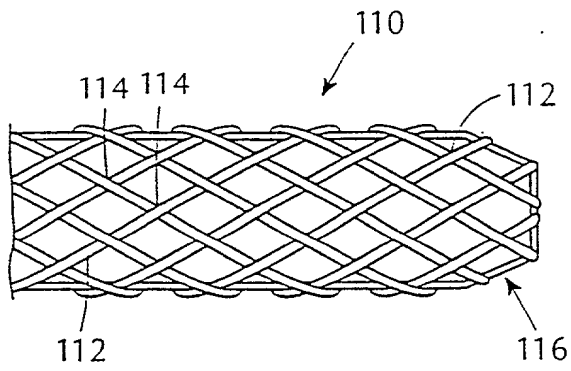


FIG. 13

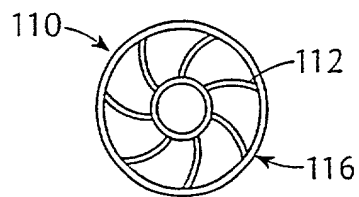
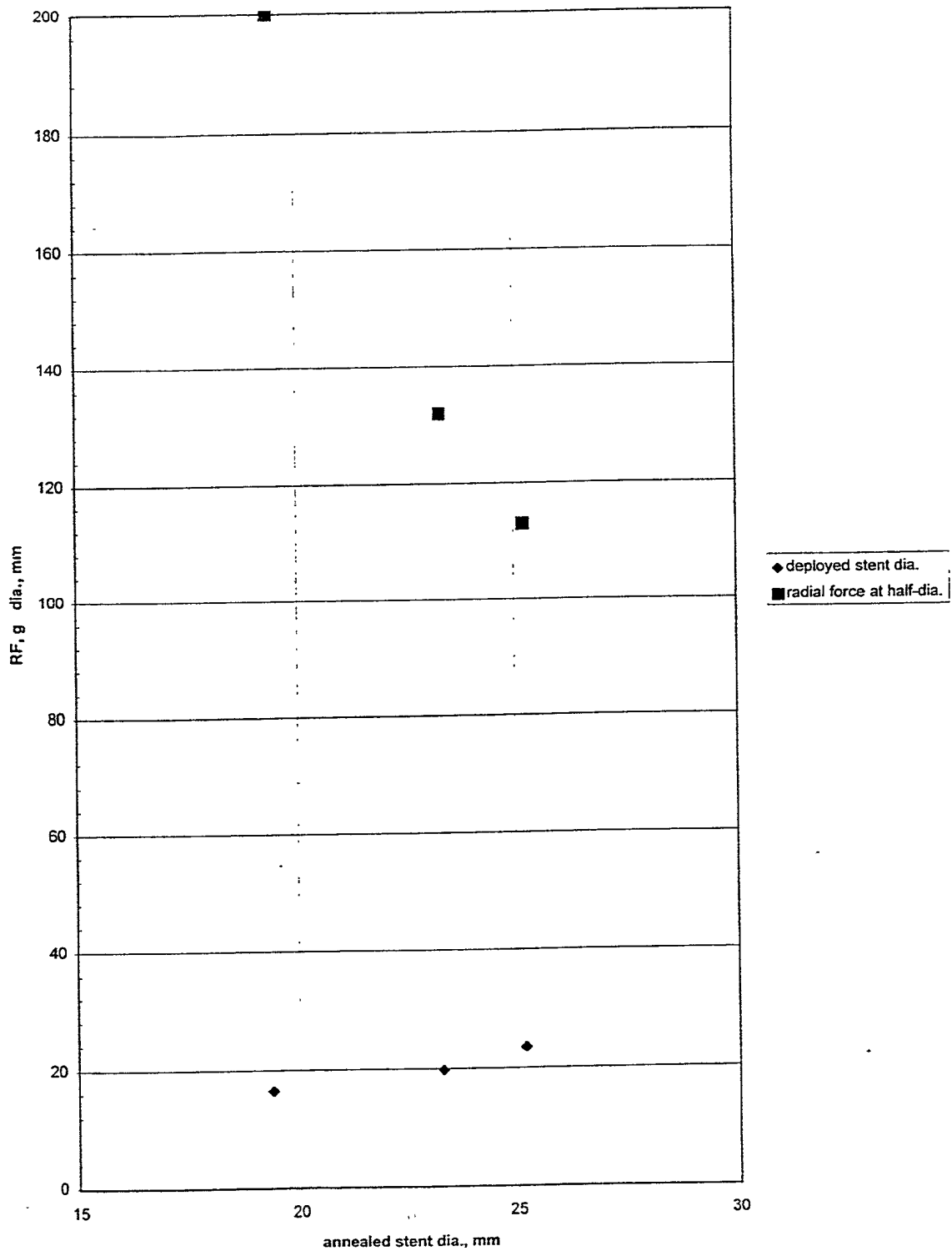


FIG. 14



Fiber No. 236-63-6 (LTR620.01) S/N Curve 8/14/98

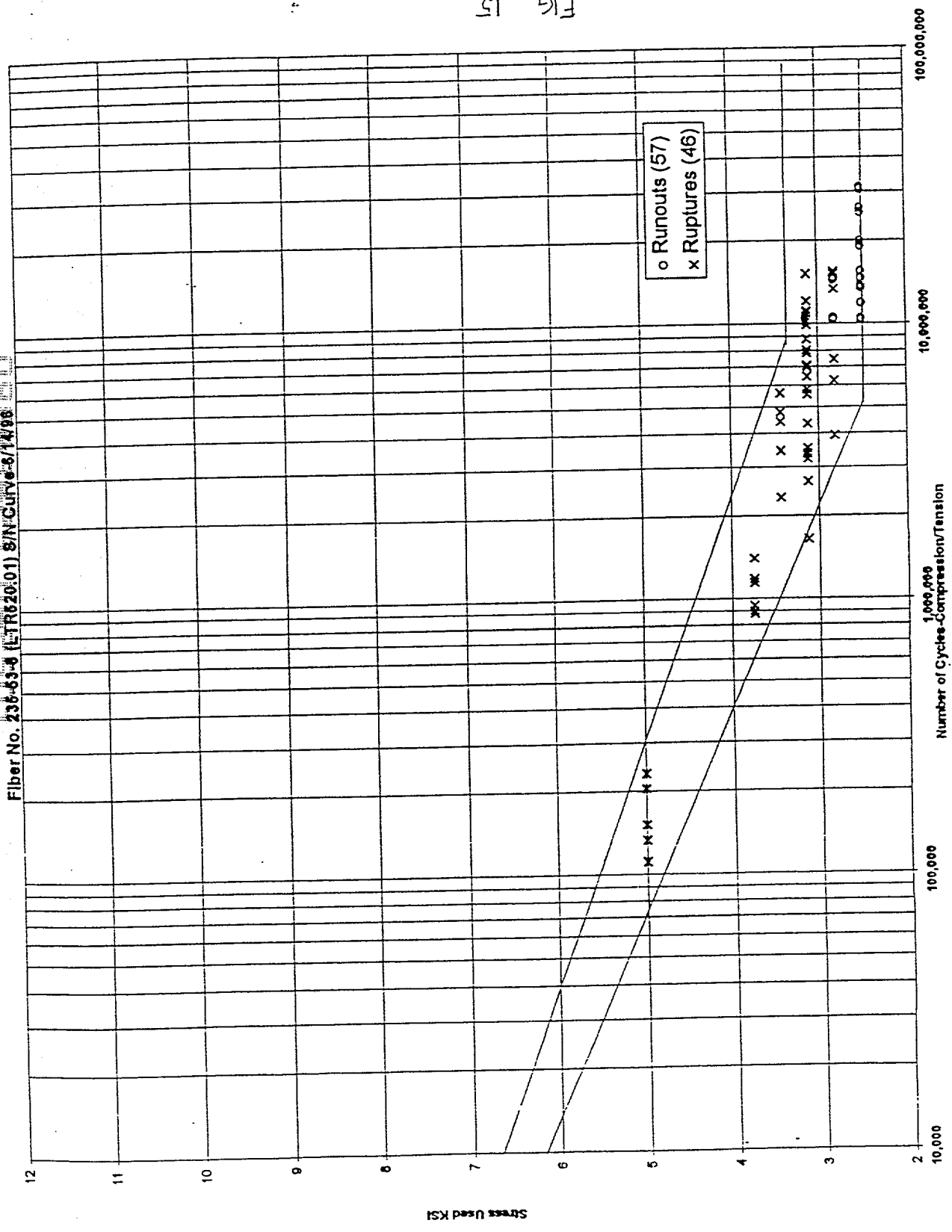


Fig. 15

Fiber No. 235-54-6 (LTR520.11) S/N Curve-5/3/96

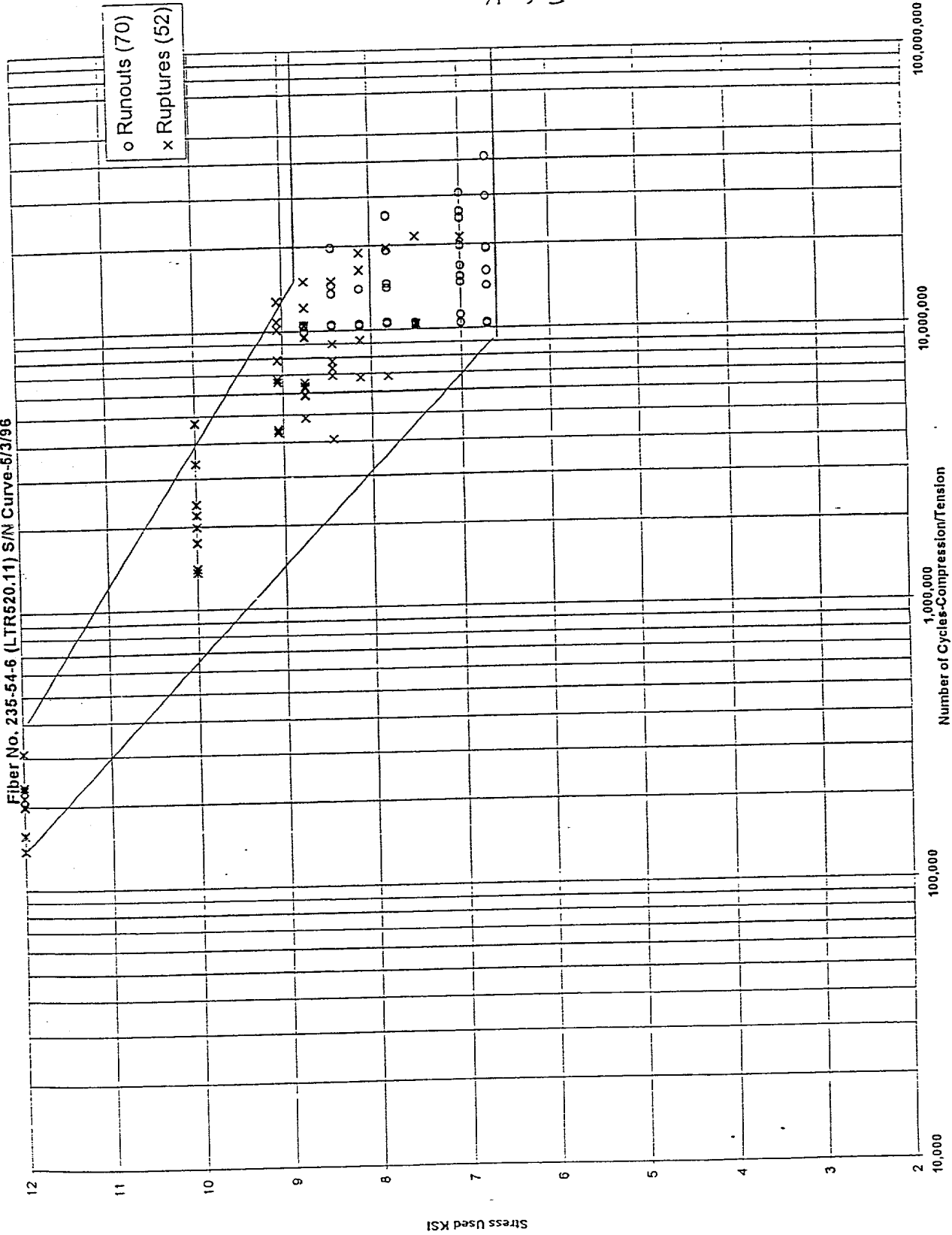


Fig. 16

Fiber No. 235-55-6 (LTR520.21) S/N Curve-5/1/96  
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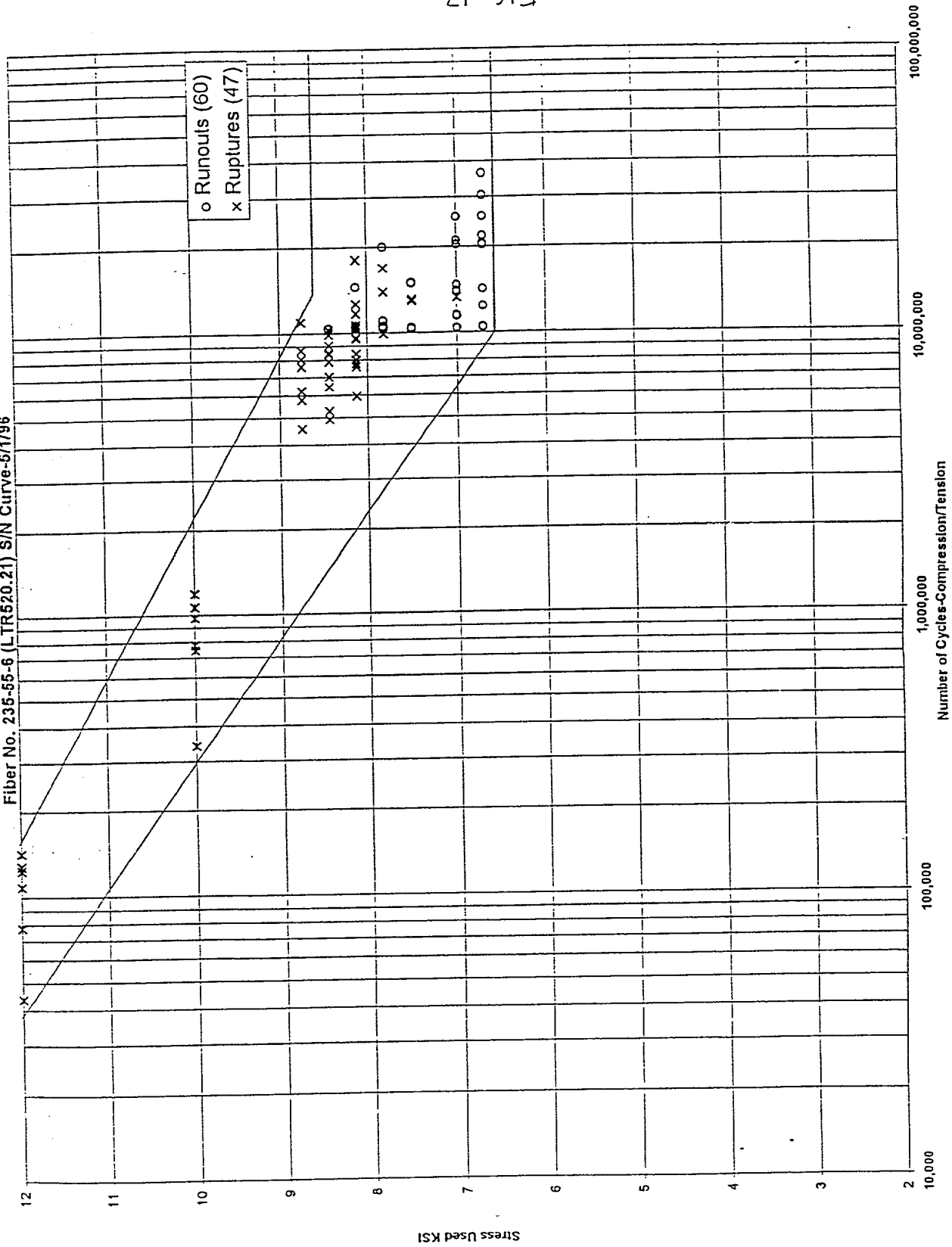


Fig. 17



Fig. 18

Fiber No. 235-56-6 (LTR520.31) S/N Curve-5/1/96

